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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/517,885

Applicant(s)

KOSKA, MARC

Examiner

Laura C. Schell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 18-21 is/are rejected.
- 7) ☒ Claim(s) 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4-25-05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (d) BRIEF SUMMARY OF THE INVENTION.
- (e) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (f) DETAILED DESCRIPTION OF THE INVENTION.
- (g) CLAIM OR CLAIMS (commencing on a separate sheet).
- (h) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

The specification is objected to because the applicant does not mention within the first paragraph the continuing data of parent application, according to 35 USC 120.

Correction is required.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

The abstract of the disclosure is objected to because the abstract is not on a separate page. The abstract is also objected to because the length is longer than 150 words. The abstract also includes language describing extensive mechanical and design details, which mimics the language of the claims. Correction is required. See MPEP § 608.01(b).

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: page 7, line 17 "curved wall 28"; page 8, line 31 "proximal end 42". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Objections

Regarding claims 1-3, 5, 6, 9, 12, and 15, the word "means" is preceded by the word(s) "spring," "guide," "locking," or "groove," in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). The examiner will consider the phrases "spring means," "guide means," "locking means," and "groove means" as "spring," "guide," "lock," and "groove" respectively.

Claim Objections

Claims 16-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). Parry discloses the same needlestick prevention sheath (figure

6), including both a first (207) and second member (208), the second of which slides, as well as a spring urging the second member to cover the needle (col. 6, lines 15-19), also illustrated in figures 6 and 7. Additionally, the reference discloses interengaging guide grooves (figure 7) and a locking mechanism, which include both a first guide part for longitudinal movement of the second member (portion including 118), and a second guide part for relative rotation of the first and second members (210). Also disclosed within the second guide part is a locking position to keep the needle covered by the second member (224).

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). Parry discloses a groove one of the first and second members (Fig. 7, 210) as well as a projection which slides within the groove (216).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry in view of Hake (US Patent No. 5,019,051). Parry discloses the same invention including a groove and projection, however Parry does not disclose a second groove and corresponding second projection, arranged in diametral opposition. Hake discloses two projections (Fig. 2, 42a and 42b) as well as two grooves (Fig. 2, 34a and 34b), both

arranged in diametral opposition, as evidenced by Figure 2 as well as referenced in col. 4, lines 52-55. Hake discloses this improvement for the purpose of additional stability of the sheath, and therefore it would have been obvious to one of ordinary skill of the art at the time of the invention to include diametrically opposing grooves and projections on Parry's invention in order to provide additional stability in retaining the sheath's position.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). Parry further discloses that the second member (Fig. 6, 208) slides within the first member (207, also see col. 6, lines 15-19).

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry. Parry discloses the claimed invention except that the groove is located on the radially interior surface of the first member (207) and the projection (216) is located on the radially exterior surface of the second member (208) (col.6, lines 19-23), i.e. the parts are reversed. Additionally, the reference discloses that the first groove of the first guide part extends longitudinally on the first member, as well as the second groove of the second guide part extends longitudinally on the first member, i.e. the parts are reversed. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to reverse the locations of the groove and the projection by placing the groove on the radially exterior surface of the second member and the projection on the radially interior surface of the first member, as well as placing the first and second grooves on the second member. This would have been an obvious design choice because Applicant has not disclosed that having the groove means on the exterior surface of the second member, the projection on the

interior surface of the first member, as well as having the first and second grooves extending longitudinally on the second member provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the groove on the radially interior surface of the first member, the projection on the radially exterior surface of the second member, and the first and second grooves extending longitudinally on the first member, because a projection on the second member can follow the track on the first member just as easily as if the positions of the track and projection were reversed. Furthermore, one would have expected Applicant's invention to perform equally well with the groove on the radially interior surface of the first member, the projection on the radially exterior surface of the second member, and the first and second grooves extending longitudinally on the first member, because Applicant states in his specification that "it would of course be possible for the groove means to be on the first member and the projection on the second member" (page 3, lines 15-16). Therefore it would have been an obvious matter of design choice to modify Parry to obtain the invention as specified in claims 5-7. This reversal of parts is obvious since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry. Parry discloses a second groove (Fig. 7, 210) parallel to the first groove (groove including positions 218 and 219), as well as an obvious rotation involved in order to move the projection from position 219 in the first groove to position 223 in the second

groove. Parry does not disclose, however, that a relative rotation of the members by 30° is necessary to move the projection from the first groove to the second groove. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to specify a certain degree of rotation between the first and second groove of Parry, such as 30°, because Applicant has not disclosed that a rotation of 30° provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a rotation of the members of 60° to move the projection from the first groove to the second groove, because the degree of rotation is merely dependent on the unspecified distance the projection must be displaced during rotation.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). Parry discloses a permanent locking recess within the second groove, which receives the projection (Fig. 7, 224).

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). Parry discloses a temporary locking position in the first groove, which receives the projection (Fig. 7, 219).

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). Parry discloses that the temporary locking position (Fig. 7, 219) causes the second member (Fig. 6, 208) to be less extended than in the permanent locking position (Fig. 7, 224) also explained in col. 6, lines 48-54.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). Parry discloses an initial locking recess (Fig. 7, 216) within another longitudinal groove (Fig. 7, groove in which locking mechanism 211 extends).

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). The reference discloses, in Figure 7, projections (211, 212, 213, 214, 215) and grooves shaped such that the first and second members can only be rotated in one direction.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry in view of the teachings of de la Fuente (US Patent No. 5,306,258). Parry discloses the claimed invention except for the grooves having one radial wall and one curved wall and projections of complimentary shape. De la Fuente, however, discloses a groove (Fig. 8, 40) with a radial wall (extending upward of component 46) and a ramped wall (47), as well as a projection with complementary shape (44). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use grooves with both a radial and curved wall because Applicant has not disclosed that grooves, having a radial and curved wall and projections of complimentary shape provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with grooves comprising a radial wall and a ramped wall as well as projections of complementary shape, since such a modification would have involved a mere change in the shape of a component, which performs the same function of allowing relative rotation of the grooves and projections in only one

direction. A change in shape is generally recognized as being within the level of ordinary skill in the art. Therefore it would have been an obvious matter of design choice to modify de la Fuente to obtain the invention as specified in claim 14. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). Parry discloses a compression spring (Fig. 6, 209) between the inner end of the second member (208) and the abutment end of the first member (207).

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Parry (US Patent No. 4,813,940). The reference discloses a syringe (Fig. 6) as the injection device, comprising a barrel (202).

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry in view of the teachings of Byrne et al. (US Patent No. 5,536,257). Parry discloses the claimed invention except for the first member of the needlestick prevention device being attached to the hub of the syringe barrel by a luer slip or luer lock connection. Byrne et al. discloses an extendable needlestick prevention sheath, whose first member (Fig. 2a, 4) is attached to a luer connector on the hub of a syringe barrel, for the purpose of securing a device to a syringe to prevent needlesticks (col. 3, lines 16-19). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Parry's device with a luer lock connection or luer slip connection, thereby connecting the first member of the needlestick prevention device to the hub of the syringe, in order to attach and secure the invention to syringes

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and provide a safer syringe for use and for prevention of accidentally being stuck by a used and uncovered needle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LCS

**KEVIN C. SIRMONS
PRIMARY EXAMINER**

